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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,408	12/12/2001	Donald R. Diehl	83590AEK	3702

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EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,408

Applicant(s)

DIEHL ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 07/16, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/12/2001.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Claims 1-21 are pending in the application.

Responses to Election/Restriction

2. Applicant's election with traverse of Group I claims 1-21, in part, in Paper No. 0704, dated July 16, 2004, is acknowledged. The traversal is on the grounds that all Groups I-V are photographic couples and thus provide common utility and structural features in the art. This is not found persuasive, and reasons are given, *infra*.

Status of Claims

3. Claims 1-21 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-21, in part, drawn to a process of preparing peptoid substituted azole compounds of formula (I), wherein the variable Y represents a carbon atom thereof; the variable Y' represents a nitrogen atom thereof; the variable Y'' represents a nitrogen atom thereof; variables R1, R2, and R3 independently represent an alkyl, aryl, alkoxy, amino, anilino, alkoxycarbonyl, carbonyl, acyl, cyano, sulfone, or sulfonamide; the variable X represents hydrogen atom, a halogen atom, a carboxy group, an acyl group, or a group bonded to the coupling position through a nitrogen atom thereof; the variable Z represents an integer 1-6; the variable L represents a single bond or a chain of atoms containing 1-10 carbons thereof, the variable a represent an integer 0 to 4.

The above mentioned withdrawn processes having various compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure from the compounds of the elected invention. The withdrawn processes having compounds contain varying functional groups (i.e., variables Y, Y' and Y'') which differ from those of the elected invention such as tetrazole, i.e., Y and Y' independently represent N, triazole, i.e., the variable Y represents N, and the variable Y' represent carbon, imidazole, i.e., the variable Y and Y' independently represent carbon, etc, which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 548 subclass 250(+) (tetrazole), class 548 subclass 262.2(+) (triazole), class 548 subclass 300.1(+) (imidazole), etc. Therefore, again, the processes having compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually.

The inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render

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another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

The invention claims 1-21, in part, embraced in above elected subject matter are prosecuted in the case. Claims 1-21, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter "a process for preparation of a peptoid substituted azole compound" without limitation of the peptoid substituted azole compound, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. No limitation of "a process of preparing a peptoid substituted azole compound" of the

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instant claim is found in the specification. Incorporation of the formula (I) from claim 14 into the claims would obviate the rejection.

5. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of making a peptoid substituted azole compound of formula (I), does not reasonably provide enablement for a process of making a peptoid substituted azole compound other than the compound of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

- 1) Nature of the invention.

The claim is drawn to a process of making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound.

2) State of the prior art.

The reference Hardewr et al. US 5,925,503 does not indicate which compounds of instant compounds may be useful in the claimed invention.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The processes of making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound, encompasses a vast number of processes. Applicant's specification does not enable the public to prepare such a numerous processes by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The art is pertaining to a process of making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound, remains highly unpredictable, see claim 1, lines 1-2. Different types of processes require various experimental procedures and without guidance that is applicable to all possible "a process of making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound", there would be little predictability in the scope of claimed methods.

5) Amount of direction and guidance provided by the inventor.

The processes are making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound. Applicant's limited guidance does not enable the public to prepare such a numerous "processes are making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound" in the specification. There is no enablement for "processes are making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound" representing various processes including an azo compound other than the compound of formula (I), etc, many of which are neither enabled nor supported in the specification.

6) Existence of working examples.

A process of making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound, encompasses a vast number of processes. Applicant's limited working examples do not enable the public to prepare such a method of "processes are making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound" in the specification. Applicants claim "processes are making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound", however, the specification provides only limited examples of the instant method, see pages 50-165.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "processes are making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous methods to perform in order to obtain "processes are making a peptoid substituted azole compound without limitation of the peptoid substituted azole compound," as claimed. Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. A suggestion to obviate the rejection would incorporate the azo compound of formula (I) into the claim, see pages 7-9.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

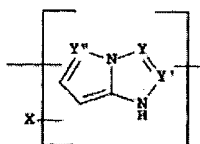
In claim 1, lines 2-4, recites the limitation "comprising reacting an amino functionalized azole compound with a resin bound oligomer bearing a terminal halogen substituent followed by cleavage of the ... in an inert solvent", is ambiguous and

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indefinite. It is unclear what the reactants and the processes are. Is a reactant an amino functionalized azole compound or a resin? Is a reactant a resin bound peptoid oligomer bearing a terminal halogen? Clarification is required, see Examples 1 and 2 of pages 46-53.

In claim 15, recites the limitation "wherein a is at least 1", is ambiguous and indefinite. It is unclear what the limitation is. Is it the variable "a" of formula (I)? Clarification is required.

In claim 16, recites the limitation "wherein the azole is selected from the group", is ambiguous and indefinite. It is unclear what the azole is. Is it the azole compound of



formula (I) or the moiety ? Clarification is required.

Objection


7. Claims 1-21 are objected as containing a non-election invention, i.e., the variable Y does not represent nitrogen, the variable Y' does not represent a carbon atom. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the elected subject matter of page 2, *supra*.


Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert Shiao, Ph.D.
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for Joseph K. McKane
Supervisory Patent Examiner
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9/14/04

September 14, 2004